FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION OF MODERNA COVID-19 VACCINE AND MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

FOR 6 MONTHS THROUGH 5 YEARS OF AGE

Your child is being offered either Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Moderna COVID-19 Vaccine, Bivalent, to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent for use in individuals 6 months through 5 years of age.[1]

Moderna COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to provide:

- **a two-dose primary series to individuals 6 months through 5 years of age; and**
- **a third primary series dose to individuals 6 months through 5 years of age with certain kinds of immunocompromise.**

Moderna COVID-19 Vaccine, Bivalent has received EUA from FDA to provide a single booster dose to individuals 6 months through 5 years of age at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine.

Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent are not FDA-approved for use in individuals 6 months through 5 years of age.

This Fact Sheet contains information to help you understand the risks and benefits of Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent may not protect everyone.

[1] You may receive this Fact Sheet even if your child is 6 years old. Children who will turn from 5 years to 6 years of age between doses in the primary series may receive, for any dose, either: (1) the Moderna COVID-19 Vaccine authorized for use in individuals 6 months through 5 years of age; or (2) Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

HOW ARE MODERNA COVID-19 VACCINE AND MODERNA COVID-19 VACCINE, BIVALENT RELATED?

Moderna COVID-19 Vaccine, Bivalent is made in the same way as Moderna COVID-19 Vaccine, but it also contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2.

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS EITHER OF THESE VACCINES?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

WHO SHOULD NOT GET MODERNA COVID-19 VACCINE OR MODERNA COVID-19 VACCINE, BIVALENT?

Your child should not get either of these vaccines if your child:

- had a severe allergic reaction after a previous dose of Moderna COVID-19 Vaccine
- had a severe allergic reaction to any ingredient of these vaccines

WHAT ARE THE INGREDIENTS IN THESE VACCINES?

Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent contain the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine

[DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HOW ARE THESE VACCINES GIVEN?
Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent will be given to your child as an injection into the muscle.

Primary Series: Moderna COVID-19 Vaccine is administered as a two-dose series, 1 month apart. A third primary series dose may be administered at least 1 month after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: Moderna COVID-19 Vaccine, Bivalent is administered as a single booster dose at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine.

HAVE THESE VACCINES BEEN USED BEFORE?
Millions of individuals 6 months of age and older have received the Moderna COVID-19 Vaccine under EUA. In a clinical trial, approximately 5,000 individuals 6 months through 5 years of age have received at least 1 dose of Moderna COVID-19 Vaccine. In other clinical trials, approximately 4,000 individuals 6 years through 11 years of age and 30,000 individuals 12 years of age and older have received at least 1 dose of Moderna COVID-19 Vaccine.

Millions of individuals 6 years of age and older have received Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) under EUA. In a clinical trial, approximately 400 individuals 18 years of age and older received 1 dose of a bivalent vaccine that differs from the Moderna COVID-19 Vaccine, Bivalent in that it contains a different Omicron component.

WHAT ARE THE BENEFITS OF THESE VACCINES?
Moderna COVID-19 Vaccine has been shown to prevent COVID-19. FDA has authorized Moderna COVID-19 Vaccine, Bivalent to provide better protection against COVID-19 caused by the Omicron variant of SARS-CoV-2.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THESE VACCINES*?*
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent. In most of these people, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with these vaccines include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection or in the groin, redness, and swelling (hardness)
- General side effects: fatigue, headache, muscle pain, chills, nausea and vomiting, fever, joint pain, irritability/crying, sleepiness, and loss of appetite

Side effects that have been reported during post-authorization use include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of these vaccines. Serious and unexpected side effects may occur. The possible side effects of these vaccines are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" or "Moderna COVID-19 Vaccine, Bivalent EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET MODERNA COVID-19 VACCINE OR MODERNA COVID-19 VACCINE, BIVALENT?
Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive either of these vaccines, it will not change your child's standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE OR MODERNA COVID-19 VACCINE, BIVALENT?
For primary vaccination for children 6 months through 5 years of age, other vaccines to prevent COVID-19 may be available under EUA. For booster vaccination for children 5 years of age who have completed primary vaccination with an FDA authorized COVID-19 vaccine, other bivalent vaccines that contain an Omicron component of SARS-CoV-2 may be available under EUA. For booster vaccination for children 6 months through 4 years of age who have completed primary vaccination with Moderna COVID-19 Vaccine, the Moderna COVID-19 Vaccine, Bivalent is the only vaccine available under EUA.

CAN MY CHILD RECEIVE MODERNA COVID-19 VACCINE OR MODERNA COVID-19 VACCINE, BIVALENT AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent at the same time as other vaccines. If you are considering having your child receive Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent with other vaccines, discuss your options with your child’s healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
If your child is immunocompromised, you may be given the option to have your child receive a third primary series dose of Moderna COVID-19 Vaccine. Immunocompromised children 6 months through 5 years of age who have completed primary vaccination with Moderna COVID-19 Vaccine may receive a single booster dose with the Moderna COVID-19 Vaccine, Bivalent. Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to have your child maintain physical precautions to help prevent COVID-19. Your child’s close contacts should be vaccinated as appropriate.

WILL THESE VACCINES GIVE MY CHILD COVID-19?
No. These vaccines do not contain SARS-CoV-2 and cannot give your child COVID-19.

KEEP YOUR CHILD'S VACCINATION CARD
When your child gets the first COVID-19 vaccine, you will get a vaccination card. Remember to bring the card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?
- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY CHILD'S VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THESE COVID-19 VACCINES?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been

seriously injured by certain medicines or vaccines, including these vaccines. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

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To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

The mRNA vaccines (those by Pfizer and Moderna) did not use a fetal cell line to produce or manufacture the vaccine. However, a fetal cell line was used in a very early phase to confirm efficacy prior to production and manufacturing.

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

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